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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,985	07/15/2003	Thomas David Starkey	N9464-ICW	3040
23456	7590	10/18/2004	EXAMINER	
WADDEY & PATTERSON 414 UNION STREET, SUITE 2020 BANK OF AMERICA PLAZA NASHVILLE, TN 37219			SNOW, BRUCE EDWARD	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/619,985	Applicant(s) STARKEY, THOMAS DAVID	
	Examiner Bruce E Snow	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 6, 7, 12, 13, 17, 23, 27 and 28 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32-34 is/are allowed.
- 6) ☒ Claim(s) 1, 5, 8-11, 14-16, 18-22, 24-26 and 29-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/15/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I in the reply filed on 9/27/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 2-4, 6-7, 12-13, 17, 23, 27-28 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group. It is noted that claims 2-4 are properly grouped in Group III, combination of the DIVOLA and VCD and are withdrawn.

Applicant's election with traverse acknowledged, however, failed to present any arguments.

Allowable Subject Matter

Claims 32-34 are allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 depends from itself.

Claim 25 depends from itself.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Regarding claim 22-23, the claimed invention is directed to non-statutory subject matter. Claim 22 positively claims the heart which is non-statutory subject matter. No rejection in view the art could be applied.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting

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directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 9-11, 20, and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Noon et al (4,731,076).

Noon et al teaches an apparatus fully capable of being inserted into a ventricle of a heart for limiting volume including:

- a. a hollow plastic sac 10 or 12 with two openings 14, 16 or 18, 20 (include valves)
- b. said sac being soft and compliant so that it will fill easily with blood to a certain, predetermined volume, but when the sac has reached capacity, no further filling is allowed.

Claims 1, 5, 8-11, 14-16, 18-21, 24, 29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Corral (5,139,517).

Corral et al teaches an apparatus for insertion into a ventricle of a heart and limits volume including:

- a. a hollow plastic sac 46 with two openings
- b. said sac being soft and compliant so that it will easily fill with blood to a certain, predetermined volume, but when the sac has reached capacity, no further filling is allowed. Said apparatus is inserted into a ventricle and the opening are connected to the annulus of the inflow and outflow valves.

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Regarding claim 14, the apparatus removes the pumping pressure from the heart wall reducing stress thereon.

Regarding the limitation "an addition to a conventional operation", which could include exploratory procedures which are inherently done.

Claims 9-11, 18-21, and 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al (2002/0169360).

Referring to at least 12A-14C, Taylor et al teaches a flexible sac 113, 139 for placement in a ventricle of a heart, said sac having a capacity for receiving a predetermined volume of blood, and said sac, when filled to capacity, appears generally in size and shape to match the size and shape of a ventricle of an undiseased human heart. The sac allows the heart to pump in a more normal fashion reducing stress on the heart wall.

Regarding at least claims 18-19, see all embodiments taught by Taylor et al.

Regarding the limitation "an addition to a conventional operation", which could include exploratory procedures which are inherently done.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25-26 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corral (5,139,517).

Corral teaches the apparatus as described the grounds of rejection above, however, is unclear if an outflow valve is used. It would have been obvious to one having ordinary skill in the art to have utilized an outflow valve in combination with said apparatus if the natural valve was damaged or deemed unsatisfactory by the surgeon.

Regarding claim 31, Corral teaches the apparatus can be used when "*the natural heart may become incapable of maintaining adequate circulation because of various disease processes, including myocardial infarction.*" It is well known in the art that this teaching includes left ventricular aneurysm. Regarding the limitation "an addition to a conventional operation", which could include exploratory procedures which are inherently done.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (703) 308-3255. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703)308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read 'BSN', with a long horizontal line extending to the right.

BRUCE SNOW
PRIMARY EXAMINER